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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,540	02/08/2002	James Arthur Hoffmann	X-11368A	4243
25885	7590	06/18/2004	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,540	HOFFMANN, JAMES ARTHUR	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/19/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to Applicant's election received Feb. 10, 2004.

Claims 1-34 are cancelled. Claims 35-53 are added. Claims 35-53 are currently pending.

Applicant's election of Group III, claims 35-52 with traverse is acknowledged. The traversal is on the grounds that insulin or sulfonylurea compounds would not provide the same benefit to a patient as the claimed compounds. Furthermore, sulfonylurea compounds have been linked to increased morbidity in patients with diabetes mellitus. Finally, the search for Group II would not create undue burden for the Examiner.

Applicant's arguments have been considered and are found persuasive. The previous restriction requirement is withdrawn.

Information Disclosure Statement(s)

Applicant's Information Disclosure Statement received April 19, 2002 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objection(s)

1. Claims 39, 44 are objected to because of the following informalities: in claim 39, in paragraph (e), after "substitution" and before "glycine", the term —of—should be added. In claim 44, line 2, "molecule" should be cancelled and replaced with —compound—in order to remain consistent with the language of claim 35. Furthermore, in claim 44, paragraph (e), the term —of—should be added after "substitution" and before "glycine". Appropriate correction is required.

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Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method for treating a person having a condition for which administration of a GLP-I compound is indicated by administering an effective amount of a formulation of claim 35. The claimed method fails to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "a condition for which administration of a GLP-I compound is indicated". Furthermore, the claimed method includes the treatment of an unspecified disease. Other than diabetes, there is no evidence, which indicates that other treatable conditions were known to Applicant. In the absence of some understanding of the conditions to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the method as claimed.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 35-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudsen et al., 6,458,924.

Knudsen et al. disclose a method of treating a patient suffering from diabetes by administering an effective amount of a composition containing GLP-1 analogues (7-37, 7-38). The pharmaceutical composition contains, in addition to the GLP-1 analogue, an isotonic agent, such as glycerol or sodium chloride, a preservative (such as phenol or cresol) and a buffer. The composition, which may be in the form of an injection solution, additionally contains a surfactant such as a polymeric surfactant, for example Tween-40, Tween 80, etc and is at a desired pH range of 3-8. Finally, Knudsen et al. teach that the particular derivative to be administered and the dosage amounts for a patient depend upon a variety of factors such as the efficacy of the derivative being administered, body weight, age, etc. Please see the abstract; col. 153, lines 45-66; col. 154, lines 36-37; col. 156, lines 28-29 and lines 62-67; col. 157, lines 5-12; col. 204, line 65 to col. 205, line 4.

With respect to the claimed pH of the composition, since Knudsen et al. establish that solubility and stability of the composition is dependent upon the pH (col. 204, line 65 to col. 206), it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the pH of the composition such that stability and solubility of the overall composition is optimized.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 35-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,358,924 in view of Knudsen et al., supra.

USPN '924 claim a stable pharmaceutical formulation comprising a GLP-1 compound (SEQ ID NO; 1, 4, 5) or derivative thereof, an anionic surfactant and preservative, wherein the pH of the composition, which is in solution form, ranges from 6.5 to 9.0. USPN '924 additionally claim a method for treating a person having a

condition for which administration of a GLP-1 compound is indicated by administering an effective amount of the claimed formulation.

USPN '924 does not claim a formulation containing a buffer and a tween polymeric surfactant. However, the Examiner refers to Knudsen et al., which disclose a stable pharmaceutical composition containing a GLP-1 derivative as well as a preservative, a buffer and a surfactant, wherein the surfactant may be a polymeric Tween surfactant or an anionic surfactant. Please see col. 153, lines 45-66; col. 154, lines 36-37; col. 156, lines 28-29 and lines 62-67; col. 157, lines 5-12; col. 204, line 65 to col. 205, line 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the claimed composition of USPN '924 to substitute the anionic surfactants with a polymeric Tween surfactant because one of ordinary skill in the art, based on Knudsen's disclosure would reasonably expect a tween surfactant to be equally effective in stabilizing the GLP-1 containing formulations.

Conclusion

Claims 35-53 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

June 14, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600